IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYOWA HAKKO BIO, CO., LTD., BIOKYOWA, INC., KYOWA HAKKO BIO U.S. HOLDINGS, INC., and KYOWA HAKKO U.S.A., INC., Plaintiffs, v. AJINOMOTO CO., INC., AJINOMOTO ANIMAL NUTRITION GROUP, INC., AJINOMOTO NORTH AMERICA, INC., AJINOMOTO HEARTLAND, INC., and AJINOMOTO WINDSOR, INC., Defendants.	**C.A. No. 17-313 (VAC-SRF)** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Kyowa Hakko Bio, Co., Ltd, Kyowa Hakko Bio U.S. Holdings, Inc., BioKyowa, Inc., and Kyowa Hakko U.S.A., Inc. (collectively "Plaintiffs"), by and through their attorneys, allege as follows:

Nature of the Action

1. Defendants Ajinomoto Co., Inc., Ajinomoto North America, Inc., and Ajinomoto Windsor, Inc. (collectively, "Defendants") infringe U.S. Patent No. RE 45,723, entitled "Process for Producing Amino Acids" (hereinafter "the '723 patent"), by one or more acts each of importation into the United States, offering to sell in the United States, or selling in the United States of Accused Products as defined in paragraph 2 below, or using a method claimed in the '723 patent to make Accused Products in the United States, as pleaded in more detail below.

2. The "Accused Products" are the amino acid L-glutamic acid and monosodium glutamate (which is a sodium salt of L-glutamic acid) and other products incorporating L-glutamic acid or monosodium glutamate, which (a) were offered for sale, sold, made, or used in the United States by one or more of the Defendants or entities under the control of a Defendant, and (b), upon information and belief, were made using a method as claimed in or equivalent to any of claims 1 and 2 of the '723 patent, either in the United States, or outside the United States and imported into the United States.

The Parties

3. Plaintiff Kyowa Hakko Bio, Co., Ltd. ("KHB") is a limited liability company organized under the laws of Japan, with its principal place of business at 1-9-2 Ohtemachi, Chiyoda-ku, Tokyo 100-0004, Japan.

4. KHB is the owner of the '723 patent.

5. Plaintiff BioKyowa Inc. ("BioKyowa") is a corporation organized under the laws of the State of Missouri, with its principal place of business at 5469 Nash Road, Cape Girardeau, MO 63702-1550.

6. Plaintiff Kyowa Hakko U.S.A., Inc. ("KHU") is a corporation organized under the laws of the State of New York, with its principal place of business at 600 Third Ave, 19th Floor, New York, NY 10016.

7. Plaintiff Kyowa Hakko Bio U.S. Holdings, Inc. ("KHH") is a corporation organized under the laws of the State of Delaware, with its principal place of business at 5469 Nash Road, Cape Girardeau, MO 63702-1550.

8. KHB and BioKyowa are leading biochemical companies that provide amino acids and other high value-added functional materials for inclusion in pharmaceutical,

medical treatment and healthcare, dietary supplement, and cosmetic products. KHU markets and sells the products of KHB and BioKyowa in the United States.

9. BioKyowa and KHU are wholly owned subsidiaries of KHH, KHH is a wholly owned subsidiary of KHB, and the income and losses of BioKyowa, KHU and KHH are included in the consolidated financial reports of KHB.

10. BioKyowa makes and sells amino acid products made using a process as claimed in the ’723 patent.

11. KHU sells amino acid products that are made by BioKyowa, KHB, and other companies controlled by KHB using a process as claimed in the ’723 patent.

12. KHB, BioKyowa, and KHU are damaged in their business by infringement of the ’723 patent.

13. Defendant Ajinomoto Co., Inc. (“AJ”) is a limited liability company organized under the laws of Japan, with its principal place of business at 15-1, Kyobashi 1-chome, Chuo-ku, Tokyo 104-8315, Japan.

14. Since about April 1, 2015, Ajinomoto North America, Inc. has been a corporation organized under the laws of the State of New Jersey, with its principal place of business at 400 Kelby Street, Fort Lee, New Jersey 07024, and has been registered as a foreign corporation in the State of Delaware.

15. On or about April 1, 2015, that New Jersey corporation succeeded to the business of Ajinomoto North America, Inc., which was a corporation organized under the laws of the State of Delaware, with its principal place of business at 400 Kelby Street, Fort Lee, New Jersey 07024.

16. The current Ajinomoto North America, Inc., incorporated in New Jersey, is liable for any acts of patent infringement alleged herein that were committed by its predecessor, the Delaware corporation of the same name.

17. Both the Delaware and New Jersey corporations named Ajinomoto North America, Inc. are referred to collectively herein as "ANA."

18. ANA is a wholly owned subsidiary of AJ.

19. Upon information and belief, ANA principally imports, manufactures, and sells cosmetic, human food, human nutritional or pharmaceutical product applications, including at least some of the Accused Products, under the general direction and control of AJ.

20. Defendant Ajinomoto Windsor, Inc. ("AW") is a corporation organized under the laws of the State of Oregon, with its principal place of business at 4200 Concours Street, Suite #100, Ontario, CA 91764.

21. Upon information and belief, AW principally imports, manufactures, and sells food products, including the Accused Product monosodium glutamate.

22. All of the Defendants other than AJ are wholly owned subsidiaries of AJ, either directly or indirectly.

23. Defendants are all members of the Ajinomoto Group, and, upon information and belief, are controlled and managed by AJ in connection with the Accused Products.

24. On information and belief, the Defendants function as an integrated organization and a single business enterprise in the manufacture of the Accused Products in inside and outside the United States, in the importation of Accused Products into the United States, and in the sale of Accused Products in the United States.

25. In particular, the Defendants hold themselves out as a single business enterprise in their advertising in connection with amino acids and use the trademark "Ajinomoto" in offering and promoting the sale of those products in the United States, without any apparent distinction regarding which Defendant is offering or would deliver those products.

26. Defendants promote Ajinomoto Group's "global cooperation system" in R&D.

27. AJ includes three R&D "institutes." Upon information and belief, one of these AJ institutes has specified the processes used by Defendants to manufacture the Accused Products.

28. Upon information and belief, AJ selects, directs and controls the methods used by Defendants to make the Accused Products.

29. Upon information and belief, AJ provides, directs, and controls intellectual property services for Defendants in connection with the Accused Products.

30. Upon information and belief, AJ has a direct financial interest in the infringing acts pled herein.

31. Upon information and belief, the assets, liabilities, income and expenditures of each of ANA and AW are included in the consolidated financial statements of AJ.

Jurisdiction

32. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271, 281, 282(a), 283, 284, and 285.

33. This Court has subject matter jurisdiction over this patent infringement action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

34. This Court has personal jurisdiction over Defendants.

35. This Court's exercise of personal jurisdiction over Defendants would comport with due process. In particular, this Court has personal jurisdiction over Defendant ANA because it is the successor to the business of the same name organized under the laws of the State of Delaware, it is registered as a foreign corporation in the state of Delaware, it has one or more agents in the state of Delaware, it has thereby availed itself of the privileges of conducting business in the State of Delaware, and it has sought protection and benefit from the laws of the State of Delaware. Upon information and belief, each of Defendants ANA and AW have regularly conducted and continue to conduct business in the State of Delaware, directly or through agents or both.

36. On information and belief, each of Defendants ANA and AW, directly or indirectly through their agents, have committed infringing activities in Delaware and in the United States by making, using, marketing, offering for sale, selling, and importing Accused Products; by offering such Accused Products for sale and placing them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in this judicial district and/or purchased by consumers in this judicial district.

37. On information and belief, Defendant AJ, directly and vicariously through its agents, including ANA and AW, has committed infringing acts in Delaware and in the United States by making, using, marketing, offering for sale, selling, and importing Accused Products; by offering such Accused Products for sale and placing them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for

sale, and/or sold by others in this judicial district and/or purchased by consumers in this judicial district.

38. On information and belief, Defendant AJ has induced acts of infringement of the ’723 patent in Delaware and in the United States by its agents, including ANA and AW, by making, using, marketing, offering for sale, selling, and importing Accused Products; by offering such Accused Products for sale and placing them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in this judicial district and/or purchased by consumers in this judicial district, all with knowledge of the ’723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the ’723 patent.

39. For example, and without limitation, upon information and belief, Defendants manufacture the Accused Product L-glutamic acid, intended for cosmetic, human food, human nutritional, or pharmaceutical product applications; offer such products for sale throughout the United States on websites controlled by AJ or ANA or both; and sell such products in Delaware and elsewhere in the United States through ANA and other agents.

40. For example, and without limitation, upon information and belief, Defendants manufacture AJI-NO-MOTO brand and unbranded Accused Product monosodium glutamate (which is a salt of L-glutamic acid) intended for human food product applications; offer such products for sale throughout the United States on websites controlled by one or more of AJ, ANA, and AW; and sell such products in Delaware and elsewhere in the United States through ANA, AW, and other agents.

41. Joinder of all three Defendants in this action is proper under 35 U.S.C. §299(a) because Plaintiffs’ right to relief is asserted against the parties jointly and arising

out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process; and questions of fact common to all defendants will arise in the action.

The Patent-In-Suit

42. The ’723 patent is entitled “Process for Producing Amino Acids” and was issued by the United States Patent and Trademark Office on October 6, 2015.

43. The ’723 patent is a reissue of U.S. Patent 7,888,078 (“the ’078 patent”), which is based on the U.S. national phase application corresponding to PCT/JP2006/307725, filed April 12, 2006. PCT/JP2006/307725 claims priority to Japanese national application JP2005-114254, filed April 12, 2005.

44. The ’723 patent was duly and legally issued, is valid and enforceable, and is currently in full force and effect.

45. A true and correct copy of the ’723 patent is attached hereto as Exhibit 1 and incorporated by reference.

46. KHB is the owner, by valid assignment, of the entire right, title and interest in and to the ’723 patent by virtue of the assignment to KHB of the ’078 patent.

47. KHB has authorized BioKwoya and KHU to use the inventions claimed in the ’723 patent.

Patent Claims

48. For convenience, representative claim 1 (as amended during reissue proceedings) is reproduced here, with paragraph identifiers [a] - [e] added for convenience of reference:

> 1. A process for producing an amino acid, which comprises:
> [a] culturing a microorganism having an ability to produce the amino acid in a medium,
> [b] adding crystals of the amino acid having an average particle size of 7 to 50 μm to the medium at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium so that the concentration of the crystals of the amino acid becomes 0.5 g/l or more,
> [c] culturing the microorganism having the ability to produce the amino acid in the medium,
> [d] allowing the crystals of the amino acid to grow to crystals of the amino acid having an average particle size of 30 μm or more and accumulate in the medium, and
> [e] recovering the crystals of the amino acid from the culture by separating the microorganism producing the amino acid and the accumulated crystals of the amino acid based on the difference in particle size or specific gravity between them.

49. Claim 2 is the same as Claim 1 except that, the "adding crystals" step [b] of Claim 1 concludes "so that the concentration of the crystals of the amino acid becomes 0.5 g/l or more," and the "adding crystals" step of Claim 2 concludes "so that the total surface area of the crystals of the amino acid in the medium becomes 0.02 m^2/1 or more."

50. Steps [b] - [e] of Claims 1 and 2 define a particular type of Direct Crystal Precipitation ("DCP") process involving the use of seed crystals.

Count I: Infringement of The '723 Patent

51. Plaintiffs incorporates the above allegations as if set forth here in full.

52. Defendants do not have a license to practice the patented inventions of the ’723 patent.

53. Upon information and belief, and without limitation, the Defendants are acting as a single business enterprise.

54. One or more of the Defendants has directly infringed claims 1 and 2 of the ’723 patent under 35 U.S.C. § 271(a) by using the patented process or equivalent steps to make Accused Products in the United States.

55. One or more of the Defendants has infringed claims 1 and 2 of the ’723 patent under 35 U.S.C. § 271(g) by importing the Accused Products into the United States or by making, selling, offering for sale, or using the Accused Products in the United States after they have been imported, using the patent process or equivalent steps.

56. One or more of the Defendants has vicariously infringed claims 1 and 2 of the ’723 patent under 35 U.S.C. § 271(a) and (g) by directing one of its agents to use the patented process or equivalent steps to make, use sell and offer for sale Accused Products in the United States.

57. One or more of the Defendants has induced infringement of claims 1 and 2 of the ’723 patent under 35 U.S.C. § 271(b) by directing one of its agents to use the patented process or equivalent steps to make Accused Products in the United States, or has induced one of its agents to import the Accused Products in the United States, all with knowledge of the ’723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the ’723 patent.

Acts of Infringement by Ajinomoto Co., Inc. ("AJ")

58. On information and belief, AJ has directly infringed one or more of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(a) & (g), by making or offering for sale each of the Accused Products in the United States through its agents, including one or more of the other Defendants.

59. On information and belief, AJ has vicariously infringed one or more of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(a) & (g), by specifying and controlling the method for making Accused Products that are imported into the United States or made in the United States through its agents, including one or more of the other Defendants.

60. On information and belief, AJ has induced infringement of one or more of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(b), by specifying and controlling the method for making Accused Products that are imported into the United States or made in the United States by its agents, including one or more of the other Defendants, and by inducing them to sell or offer to sell the Accused Products into the United States, or import the Accused Products in the United States, all with knowledge of the '723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the '723 patent.

Acts of Infringement by Ajinomoto North America, Inc. ("ANA")

61. On information and belief, ANA has directly infringed one or more of claims 1 and 2 of the '723 patent, in violation of 35 U.S.C. § 271(a) & (g), by importing or making or selling or offering for sale each of the Accused Products for sale in the United States by itself or through its agents, including one or more of the other Defendants, and by selling

each of the Accused Products for sale in the United States, both directly and through its agents.

62. As an example, upon information and belief, of importation of an Accused Product by ANA, on May 1, 2016, over 117,000 kg of L-glutamic acid shipped from Antwerp, Belgium by Ajinomoto Foods Europe S.A.S. arrived in the Port of Virginia in Norfolk, Virginia for consignee Ajinomoto North America Inc. (Bill of Lading YMLUT851010745). *See* Exhibit. 4.

63. ANA claims to operate the only pharmaceutical L-amino acid manufacturing plant in the United States in Raleigh, NC, and claims that its Raleigh plant produces both individual amino acids as well as custom-blended amino acid mixtures.

64. Upon information and belief, ANA produces glutamic acid at its plant in Eddyville, Iowa.

65. Upon information and belief, the process used by ANA to produce glutamic acid at its plant in Eddyville, Iowa includes steps literally corresponding to each of steps [a] and [c] – [e] of claims 1 and 2 of the ’723 patent, set forth in paragraphs 48-50 above.

66. Upon information and belief, the process used by ANA to produce glutamic acid at its plant in Eddyville, Iowa includes a step literally corresponding to or the equivalent of adding seed crystals of glutamic acid to cause precipitation of glutamic acid crystals as claimed in step [b] of claims 1 and 2 of the ’723 patent, set forth in paragraphs 48-50 above.

67. On information and belief, ANA has vicariously infringed one or more of claims 1 and 2 of the ’723 patent, in violation of 35 U.S.C. § 271(a) & (g), by specifying and

controlling the method for making Accused Products imported into the United States or made in the United States by its agents, including one or more of the other Defendants.

68. On information and belief, ANA has induced infringement of claims 1 and 2 of the ’723 patent, in violation of 35 U.S.C. § 271(b), by specifying and controlling the method for making Accused Products imported into the United States or made in the United States by its agents, including one or more of the other Defendants, and by inducing them to sell the Accused Products in the United States, or import the Accused Products into the United States, all with knowledge of the ’723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the ’723 patent.

Acts of Infringement by Ajinomoto Windsor, Inc. (“AW”)

69. On information and belief, AW has directly infringed one or more of claims 1 and 2 of the ’723 patent, in violation of 35 U.S.C. § 271(a) & (g), by making or offering for sale and selling the Accused Product monosodium glutamate in the United States, both directly and through its agents.

70. On information and belief, AW has induced infringement of claims 1 and 2 of the ’723 patent, in violation of 35 U.S.C. § 271(b), by inducing its agents to sell the Accused Product monosodium glutamate in the United States, or import the Accused Products into the United States, all with knowledge of the ’723 patent and with knowledge or willful blindness to the fact that the induced acts infringe one or more claims of the ’723 patent.

Evidence of Use of an Infringing Method and the Presumption of Infringement

71. Plaintiffs specifically assert that the Accused Products were made by a process which infringes one or more of claims 1 and 2 of the '723 patent, either literally or under the doctrine of equivalents.

72. Plaintiffs rely in part on 35 U.S.C. § 295 to satisfy their burden of pleading infringement and to cast the burden of proof of noninfringement on Defendants.

73. Section 295 states:

> In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds-
>
> (1) that a substantial likelihood exists that the product was made by the patented process, and
>
> (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

74. The House Report on Section 295 describes the purpose of the presumption it creates as follows:

> This presumption addresses a great difficulty a patentee may have in proving that the patented process was actually used in the manufacture of the product in question in those cases, where the manufacturer is not subject to discovery under the Federal Rules of Civil Procedure. For example, patent owners will frequently be unable to obtain information concerning the nature of processes being practiced by foreign manufacturers. Shifting the presumption should create no substantial burden, as an accused infringer should be in a much better position to establish that the product was made by another method.

H.R. Rep. 100-60, p.16 (1987).

75. To satisfy Section 295, the patentee need only present evidence that would support a reasonable conclusion that the accused product was made by the patented process.

76. The patentee need not show that the patented method was the only commercially method available before the burden-shifting presumption of Section 295 applies.

77. Defendants have not publically disclosed the processes used to make their Accused Products, except in some cases to state that a process based on fermentation of microorganisms is used.

78. Plaintiffs have no direct evidence of some steps of the processes used by Defendants to make their Accused Products because Defendants have not publically disclosed the processes they use to make their Accused Products.

79. The communications between the parties and available technical evidence identified in paragraphs 81 – 91 below demonstrate (1) the existence of a substantial likelihood that the Accused Products were made by the patented process and (2) that the Plaintiffs have made a reasonable effort to determine the process actually used in the production of the Accused Products and were unable so to determine.

80. Therefore, pursuant to 35 U.S.C. § 295, each of the Accused Products should be presumed to have been made by a process as claimed in at least one of claims 1 and 2 of the ’723 patent, and the burden of establishing that the Accused Products were not made by the process shall be on the Defendants.

Communications Between the Parties

81. Representatives of AJ approached KHB about obtaining a license under the ’723 patent and foreign counterparts in November 2014 and discussed the subject with KHB on several occasions thereafter. Those discussions have not resulted in a license agreement.

82. Plaintiffs' attorneys wrote to each of AJ and ANA on or about June 9, 2016, requesting that they disclose the process used to manufacture their Accused Products to Plaintiffs' attorneys and to Plaintiffs' expert, Dr. Ronald Rousseau, under a Non-Disclosure Agreement ("NDA"), requesting a response within 30 days. A representative request letter, sent to AJ, is Exhibit 2 to this Complaint.

83. An attorney responded by letter dated July 5, 2016 on behalf of Ajinomoto entities, including AJ, and ANA. That "Response Letter" is attached to this Complaint as Exhibit 3.

84. The Response Letter ignored Plaintiffs' request for disclosure under an NDA.

85. The Response Letter addressed only one limitation of the '723 patent claims, the "adding crystals" step [b], saying:

> Both independent claims of the '723 patent require "adding crystals of the amino acid having an average particle size of 7 to 50 μm to the medium" in which a microorganism is cultured. Ajinomoto's processes for manufacturing L-tryptophan, L-valine, and L-glutamine do not add crystals of the amino acid to the medium, as claimed. And although Ajinomoto's process for L-glutamic acid includes adding crystals of the amino acid, the average particle size of such crystals is much greater than the maximum of the range claimed in the '723 patent.

86. The Response Letter essentially admits that Defendants infringe the limitations of the '723 patent claims by their process for making L-glutamic acid, except for the argument that they add "crystals of the amino acid, the average particle size of such crystals is much greater than the maximum of the range claimed in the '723 patent."

87. That statement does not reveal how Defendants' attorneys have interpreted "average particle size" in the '723 patent claims.

88. Plaintiffs and Defendants have a continuing dispute about the interpretation of "average particle size."

89. Upon information and belief, in preparing the Response Letter, Defendants' attorney did not interpret the term "particle size" in the context of the '723 patent as meaning "the diameter of a spherical particle having the same particle volume as the particle being measured," as would be determined-for example-by the SK LASER MICRON SIZER LMS-24 mentioned in the '723 patent.

90. Upon information and belief, if the term "particle size" in the context of the '723 patent is interpreted as meaning "the diameter of a spherical particle having the same particle volume as the particle being measured," Ajinomoto's process for L-glutamic acid that is referred to in the Response Letter infringes at least one claim of the '723 patent, either literally or under the Doctrine of Equivalents.

91. On July 20, 2017, after the original Complaint was filed in this action, Defendants' counsel produced affidavits from three Ajinomoto employees stating that Ajinomoto did not use seed crystals in their methods for manufacturing L-tryptophan, L-valine, and L-glutamine. On August 2, 2017, Plaintiffs' attorneys received further assurances from Ajinomoto's U.S. attorneys representing Ajinomoto in this action that (1) Ajinomoto Heartland, Inc., has not and does not make in the United States, either glutamic acid or monosodium glutamate, (2) Ajinomoto Animal Nutrition Group, Inc. has not and does not import into the United States, or make, use, sell, or offer for sale in the United States either glutamic acid or monosodium glutamate, and (3) the Ajinomoto parties (Ajinomoto Co., Inc., Ajinomoto Animal Nutrition Group, Inc., Ajinomoto North America, Inc., Ajinomoto Heartland, Inc., and Ajinomoto Windsor, Inc.) have not imported and do not

import into the United States, or make, use, sell, or offer for sale in the United States, any amino acids made by a process using seed crystals of the amino acid, other than the process used to make glutamic acid at the Eddyville, Iowa plant of Ajinomoto North America, Inc.

92. Plaintiffs have relied on representations made by Defendants named in the original Complaint and their U.S. attorneys in omitting from this Amended Complaint accusations against original Defendants Ajinomoto Heartland, Inc. and Ajinomoto Animal Nutrition Group, Inc., and in omitting any accusation of infringement with respect to amino acids other than L-glutamic acid, which omitted accusations are withdrawn without prejudice

Technical Evidence

93. Upon information and belief, manufacturers of biologically and chemically produced products rarely disclose the processes that they use, especially when there is risk of patent infringement.

94. The Defendants state on their company websites that they use a fermentation process to produce the amino acid, L-glutamic acid

95. Defendants' Response Letter did not deny culturing a microorganism (fermentation), as claimed in steps [a] and [c] of claims 1 and 2 of the '723 patent, is used in producing the Accused Products.

96. Use of a fermentation process satisfied step [a] of claims 1 and 2 of the '723 patent.

97. Upon information and belief, Defendants have not publicly disclosed other steps used in producing the amino acid L-glutamic acid.

98. Upon information and belief, Defendants' monosodium glutamate Accused Product is a sodium salt of L-glutamic acid, and is made from L-glutamic acid.

99. Steps [b] – [e] of claims 1 and 2 of the '723 patent define a DCP process, in which the amino acid grows and accumulates in the medium while culturing of the microorganisms continues, and the crystals are recovered by separation based on particle size or specific gravity.

100. Food and pharmaceutical grade Accused Products have been highly purified following initial crystallization steps; therefore, it is not practical by product testing to determine whether a DCP process was used in producing Defendants' food and pharmaceutical grade Accused Products.

101. Upon information and belief, highly purified food or pharmaceutical grade L-glutamic acid is available from some of the Defendants in the United States.

102. There is a substantial likelihood that the method used to make the Accused Products employs steps [b] – [e] of claims 1 and 2 of the '723 patent or equivalent steps because of the evidence identified in paragraphs 103 – 114 below.

103. Upon information and belief, the patented process has substantially greater production efficiency as compared with other commercial processes for producing amino acids.

104. Because they knew of or likely knew of the '723 patent or its parent '078 patent, as indicated by the communications identified above, it is highly likely that the Defendants knew of the advantages of the specific processes claimed in the '723 patent.

105. In particular, there is a substantial likelihood that the Accused Products were made by a process including step [b], using seed crystals having an average particle size of 7

μm to 50 μm to cause precipitation as claimed in that step, or an equivalent of that step, because Defendants knew of the '723 patent's disclosure and that step [b] is superior to using other materials or methods to initiate precipitation, such as surfactants, or adjusting the temperature or pH of the culture medium, because those other materials and methods do not suppress the growth of microcrystals, and are therefore less efficient.

106. The use of surfactants can also increase costs of purification, separation, and wastewater treatment as compared with the patented process.

107. There is a substantial likelihood that the Accused Products were made by a process including steps [b] – [e] or equivalent steps because that process is not only less likely to produce undesired microcrystals, but it also produces larger crystals following growth in step [d], which makes it easier to recover a high percentage of the amino acid in the resulting crystals in step [e].

108. There is a substantial likelihood that the Accused Products were made by a process using crystals having a minimum average particle size of 7 μm or greater to cause precipitation, as claimed in step [b], as compared with using smaller crystals, because the resulting larger crystals following growth in step [d] makes it easier to recover resulting crystals in step [e].

109. There is a substantial likelihood that the Accused Products were made by a process using crystals having a maximum average particle size of 50 μm or less to cause precipitation as claimed in step [b] or an equivalent, as compared with using larger crystals, because (1) the rate of growth of crystals in step [d] is dependent on the surface area of the added crystals, and (2) the surface area per unit volume of the added crystals decreases as average particle size increases, so—all other factors being equal—smaller crystals of a given

total volume will have more total surface area and will permit faster growth as compared with larger crystals having the same total volume.

110. There is a substantial likelihood that the Accused Products were made by a process in which the crystals were added to the medium in the size range claimed in step [b] of claims 1 and 2, "at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium," or an equivalent step, because that is an optimum condition for causing precipitation and permitting the microorganism to continue producing the amino acid in step [c].

111. There is a substantial likelihood that the Accused Products were made by a process of continuing to culture the microorganisms during crystal precipitation, as in step [c], because of the greater productivity as compared with terminating culturing.

112. There is a substantial likelihood that the Accused Products were made by a process allowing the crystals of the amino acid to grow to crystals of an average particle size of 30 μm or more and accumulate in the medium, as claimed in step [d], because this particle size allows for a more efficient recovery of the crystals in step [e].

113. There is a substantial likelihood that the Accused Products were made by a process in which accumulated crystals were recovered by separating them from microorganisms, "based on the difference in particle size or specific gravity between them," as claimed in step [e] of claims 1 and 2, because the amino acid is produced in crystalline form in the DCP process and the method of step [e] is more efficient than alternatives for recovery of amino acid crystals, both in terms of time and energy.

114. Defendants' Response Letter (Exhibit 3) does not deny use of steps [c] – [e] in producing the Accused Products.

Conclusion

115. There is a substantial likelihood that the Accused Products were made by the patented process or equivalent steps, satisfying part (1) of 35 U.S.C. § 295, based on (a) the failure of Defendants to disclose their process for manufacturing the Accused Products to Plaintiffs' attorneys and expert under an NDA as discussed in paragraphs 81 and 82 above, (b) the incomplete noninfringement arguments made by Defendants' attorney in his Response Letter (Exhibit 3), identified in paragraphs 83 – 89 above, and (c) the technical evidence identified in paragraphs 93 – 115 above.

116. The same evidence demonstrates that Plaintiffs have made a reasonable effort to determine the process actually used in the production of the Defendants' Accused Products and was unable to so determine, satisfying part (2) of 35 U.S.C. § 295. This is further shown by Plaintiffs' efforts to narrow the issues and focus the dispute through ongoing discussions after the original complaint was filed.

117. Therefore, pursuant to 35 U.S.C. § 295, the Accused Products should be presumed to have been made by the patented process as asserted herein, and the burden of establishing that the Accused Products were not made by the patented process shall be on the Defendants.

118. Plaintiffs have been damaged by Defendants' infringing conduct and will continue to be damaged unless Defendants are enjoined from further infringement.

119. Upon information and belief, Defendants' infringing acts constitute willful infringement.

Demand For Jury Trial

120. Plaintiffs hereby demand a trial by jury on all issues appropriately tried to a jury.

Prayer For Relief

WHEREFORE, Plaintiffs respectfully prays for entry of judgment as follows:

121. That Defendants have directly infringed, either literally or under the doctrine of equivalents, one or more of claims 1 and 2 of the ’723 patent.

122. That Defendants have induced infringement of one or more of claims 1 and 2 of the ’723 patent.

123. That Plaintiffs are entitled to, and should recover, all damages to which Plaintiffs are entitled under 35 U.S.C. § 284, but in no event less than a reasonable royalty;

124. That Defendants be ordered to provide an accounting;

125. That Plaintiffs, as the prevailing party, shall recover from Defendants all taxable costs of court;

126. That Plaintiffs shall recover from Defendants all pre- and post-judgment interest on the damages award, calculated at the highest interest rates allowed by law;

127. That this case is exceptional and that Plaintiffs therefore shall recover their attorney’s fees and other recoverable expenses, under 35 U.S.C. § 285;

128. That, pursuant to 35 U.S.C. § 283, Defendants are permanently enjoined from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product made using a process covered by the claim 1 or claim 2 of the ’723 patent; and

129. That Plaintiffs shall recover from Defendants such other and further relief as may be appropriate.

Dated: August 7, 2017

FISH & RICHARDSON P.C.

By: */s/ Ronald P. Golden III*

Douglas E. McCann (No. 3852)
Ronald P. Golden III (No. 6254)
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: (302) 652-5070
dmccann@fr.com; golden@fr.com

John B. Pegram
John S. Goetz
Ron F. Vogel
FISH & RICHARDSON P.C.
601 Lexington Ave., 52nd Floor
New York, NY 10222-4611
Telephone: (212) 765-5070

Attorneys for Plaintiffs Kyowa Hakko Bio Co., Ltd., BioKyowa, Inc., Kyowa Hakko Bio U.S. Holdings, Inc., and Kyowa Hakko USA, Inc.